Quality Improvement Through Investigation of External Quality Assessment Discordant Findings

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ABSTRACT

Context: Quality Management Program—Laboratory Services (QMP–LS) provides mandatory external quality assessment (EQA) of laboratories in Ontario. Participants are required to formally investigate discordant findings and submit a structured report to QMP–LS for analysis.

Objective: To provide guidance to laboratories in cause-analysis, identification and monitoring of corrective action.

Methods: Participants were given instructions on root cause analysis of error. Participants reporting EQA survey results outside of acceptable limits then received a form designed to investigate errors. The responses were categorized as clerical, method, technical or random errors.

Results: *Clerical Errors:* Most were transcription errors. *EQA Material Errors:* There were relatively few material errors. All involved incorrect storage of material. *Method Errors:* In clinical chemistry and hematology, most errors were instrument-related including method validation, maintenance and calibration and/or variation associated with reagents. Some QC limits were too wide. Other errors included use of outdated or non-validated reference intervals. In microbiology and transfusion medicine, errors were associated with inadequately documented processes or procedures. *Technical Errors:* These were associated with specimen preparation and/or handling, failure to act on QC results, failure to follow documented procedures, inexperience or simply poor technique. *Random Error:* This was assigned largely because the cause was unknown. *Root Cause:* The root cause for the error was frequently not identified in participant responses. When identified, the most commonly cited cause was lack of awareness or understanding by laboratory staff. *Corrective Action:* Most corrective actions were appropriate, and included re-writing of procedures and re-education and training of staff.

Conclusions: Categorization of discordant findings in EQA surveys assists laboratories in identifying opportunities for improvement and developing root cause analysis and corrective action.

CONTEXT

In Ontario, Canada, the Ministry of Health and Long-Term Care, under the Laboratory Specimen Collection Centre Licensing Act, licenses all medical/clinical laboratories. As a condition of the licence each laboratory is required to participate in the Quality Management Program—Laboratory Services (QMP–LS). The Ontario Medical Association, acting as a deemed agent of the Minister of Health, provides this program. QMP–LS operates the External Quality Assessment Division (QMP–EQA) and the Ontario Laboratory Accreditation Division.

QMP–EQA assesses participating laboratories using three tools; challenge surveys, patterns-of-practice surveys, and method-related questionnaires. This report deals only with the investigation of discordant findings in the challenge surveys (proficiency test surveys). When a laboratory submits a finding on an EQA challenge that differs from its peers, or which does not meet the target for the challenge, an opportunity exists to investigate the root cause and identify corrective actions. In 2003, QMP–LS provided its participants with guidelines for structured root cause analysis. For the past two years, each laboratory has been asked to use these guidelines and report its findings on a discipline specific investigation form as part of its response.

OBJECTIVES

The objectives of QMP–LS in initiating this process were to:

- Provide guidance to laboratories on the structured investigation of discordant findings
- Monitor root cause analysis resulting from the investigation
- Share common cause of discordance and associated corrective actions with participating laboratories
- Contribute to improvement of laboratory services and method performance
- Assist Ontario laboratories in meeting accreditation requirements

METHODS

Over 250 medical laboratories participated in more than 100 QMP–LS challenge surveys according to their testing profile. The scope and annual volume of EQA surveys administered are shown in Table 1.

Table 1: Scope and Frequency of QMP–LS

Test Class	Surveys	No. of Surveys per year
Microbiology	Bacteriology	10
	Parasitology	2
	Mycology	2
	Virology	10
Chemistry	Routine	15
	Drugs	9
	Endocrinology	4
	Enzymes	6
	Immunology	3
	Lipids	3
	Maternal Serum Screen	4
	POCT (Glucometers)	2
Hematology	Routine	7
	Bone Marrow	3
	Coagulation	6
	Flow Cytometry	7
	Morphology	3
	Red Cell Disorders	5
Transfusion Medicine	Routine	5
Pathology	Cytology	2
	Histotechnology	2
Genetics	Cytogenetics	4
	Inherited Diseases	2

EQA Challenge Surveys

Following examination of the challenge materials, each laboratory was required to submit results on a structured worksheet. The findings were collated and analyzed for presentation to the peer-group scientific committee responsible for the survey assessment. When the submitted results did not meet the designated target values for the challenges, the laboratory was identified as having a discordant finding. The laboratory was advised of the assessment and received a discipline-specific form to be used as the basis of an internal investigation of cause.

The completed form was returned to QMP–EQA for collation and further action, as necessary. The responses were categorized in a manner similar to that described in the CLSI (NCCLS) Guide GP27-A *Using Proficiency Testing (PT) to Improve the Clinical Laboratory*.

Contributing causes of discordant results were categorized as:

- Technical – Attributable to actions of laboratory staff
- Method/equipment – Attributable to test procedure, kit or automated system
- Clerical – Incorrect transcription of results to EQA reporting worksheet
- Material – Attributable to EQA material
- Random or Unknown – Random error or cause unknown

RESULTS

The amount of information provided on the investigation forms varied. Many participants elected to provide responses by letter. Results for 2003 are presented and a comparison made between these and 2004 results. Figures 1–5 display the categorization of discordances by discipline for 2003 and each one includes a brief description of cause. The error rate was calculated by dividing the number of discordant results by the total number of results assessed or "opportunities for error." The opportunities for error vary by discipline by survey. In 2003, the overall error rate for all disciplines was 1.1%. The majority of causes were related to methodology or technical performance.

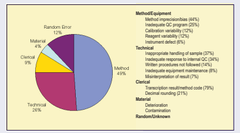

Figure 1: Contributing Causes of Clinical Chemistry Discordant Results (n=639)

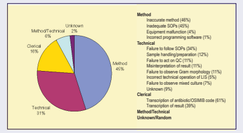

Figure 2: Contributing Causes of Bacteriology Discordant Results (n=160)

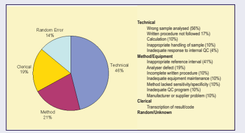

Figure 3: Contributing Causes of Analytical Hematology Discordant Results (n=154)

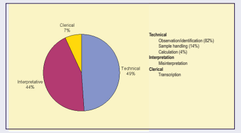

Figure 4: Contributing Causes for Hematology-Morphology/Bone Marrow Discordant Results (n=59)

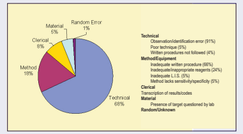

Figure 5: Contributing Causes for Transfusion Medicine Discordant Results (n=206)

Table 2 lists the most common causes by category of discordance.

In several instances when random error was identified as the cause of discordance, the investigation showed that the same result was actually achieved on repeat investigation, indicating an unknown, systematic error.

Root Cause: The root cause for the error was frequently not identified in participant responses. When identified, the most commonly cited cause was lack of awareness or understanding by laboratory staff. *Corrective Action:* Most corrective actions were appropriate for contributing causes and included re-writing of procedures and re-education and training of staff.

Results for 2004 were comparable with those identified in 2003. The overall error rate was 1.2%. Figure 6 demonstrates the comparison of categories for the two years. In 2004, methodology remained the leading cause of error and again included problems associated with performance of automated systems and use of inadequately documented methods for patient tests and/or quality control program. The percentage of technological errors was slightly reduced with most of the causes being related to lack of attention to procedures, lack of response to QC results and inadequate handling of samples. The third leading cause was clerical error, largely associated with transcription of results to the EQA analysis worksheets.

Table 2: Common Causes of Error by Category

Technical • Specimen preparation/handling bias • Failure to follow procedures • Failure to act on QC results • Misinterpretation of results • Observation errors • Inadequate equipment maintenance • Poor technique	**Method/Equipment** • Instrument imprecision/ • Lack of method validation • Calibration variability • Reagent variability/quality • Instrument defects • Inadequate QC program • Inadequate procedures
Clerical • Transcription of results/codes/units • Decimal rounding	**Material** • Incorrect storage

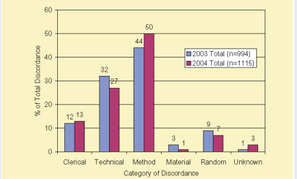

Figure 6: Comparison of EQA Discordant Findings (2003 vs. 2004)

DISCUSSION AND CONCLUSIONS

External quality assessment provides a unique sampling of laboratory output that identifies problems with laboratory performance not always detectable by internal quality assurance activities. For this reason, understanding the cause of error in an EQA survey provides a tangible basis for quality improvement initiatives.

Application of a problem-solving process to the investigation of discordant results in EQA surveys provided guidance for participants in identifying contributing causes of error and appropriate corrective action. Categorizing the causes helped to identify common causes of error among laboratories and disseminating this information among participants identified opportunities improvement for all.

After two years of operation laboratory participants are not yet comfortable with root cause analysis and tend to limit the investigation without assessing the fundamental underlying cause. Since this implies that errors in EQA, and potentially in patient tests may reoccur, further education on root cause analysis is required to promote continuous improvement.

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